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(54) Title: DUAL CATHETHER ASSEMBLY (57) Abstract <p>The present invention relates to a combination device comprising two catheters, or a dual catheter assembly, for use in vascular procedures such as pre- and post-dilatation, direct primary stenting and multiple stenting, wherein the shaft of the first catheter functions as a guidewire for the second catheter. The dual catheter assembly comprises a first balloon catheter and a second balloon catheter wherein the second balloon catheter is slidably disposed on the shaft of the first balloon. In preferred embodiments, the first catheter is a low profile balloon on a wire catheter and the second catheter is a full size balloon catheter having a plurality of balloons mounted thereon. Alternatively, the first catheter is a low profile over the wire catheter, and the second catheter is a single operator exchange catheter. Optionally, a stent is carried by at least one of the balloons on the second catheter. In more preferred embodiments, the second catheter includes a manifold that may be used to inflate and deflate any combination of the plurality of balloons <i>via</i> a single port or multiple ports. The dual catheter assembly of the present invention is especially useful in vascular procedures such as angioplasty, progressive/multiple angioplasty, and stent delivery.</p>		

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DUAL CATHETER ASSEMBLY

This application is a continuation-in-part of U.S. Application No. 09/071,018, filed May 1, 1998, which is incorporated herein by reference in its entirety.

BACKGROUND

The present invention generally relates to medical catheters. More particularly, the present invention relates to a combination device comprising two telescopic catheters, or a dual catheter assembly, for use in vascular procedures wherein the second catheter is capable of being slidably disposed over the shaft of the first catheter.

Although used in a variety of medical procedures, multiple balloon catheters are most widely associated with percutaneous transluminal coronary angioplasty.

The procedure typically involves advancing a balloon catheter to a partially blocked coronary artery and inflating one or more balloons at the blockage site. The inflated balloons stretch and/or fracture the blockage thereby enlarging the opening of the occluded vessel. In some cases, a stent is also deployed to further enlarge the opening and to prevent the weakened vessel from collapsing.

In general, separate balloon catheters are used for performing angioplasty and for delivering stents. As a result, a physician performing angioplasty followed by the implantation of one or more stents may use multiple devices. For example, the procedure may start with a floppy tip guidewire followed by a low profile balloon catheter riding over the guidewire to predilate an occluded vessel. Once the vessel is predilated, progressively larger balloon catheters may

be navigated to the stenosis, used and then withdrawn in succession to sufficiently enlarge the opening. Another balloon catheter bearing a stent may be used to deliver the stent to the lesion site. Should additional stents be required, additional balloon catheters bearing stents may be used. Finally, the vessel may also be post-dilated using yet another balloon catheter. The use of multiple devices is both time-consuming and further runs a risk of abrupt reclosure of the vessel while the devices are being exchanged, e.g., while switching from an angioplasty catheter to a stent delivery catheter.

Attempts have been made to design devices that perform more than one function during vascular procedures. For example, U.S. Patent No. 5,035,686 discloses a low profile balloon on a wire catheter that is designed to also act as guidewire for a second catheter. Because the low profile balloon catheter may also function as an independent guidewire, it would remain in the vessel and any subsequent catheter would be threaded over its shaft. However, because the subsequent devices are necessarily off-the-shelf catheters often made by different manufacturers, the desired combination of catheters either may not work well together, or may not be compatible with each other.

Another example of a catheter that performs more than one function is described by U.S. Patent No. 5,226,889, which discloses a multiple balloon catheter wherein one of the balloons carries a stent. The idea behind this device is that this single catheter may be used for performing both angioplasty and stent delivery. However, multiple catheters are still required in most cases. Due to the stent, these combination catheters typically are stiffer and have larger profiles and thus are not generally able to navigate the occluded vessel without the vessel being pre-dilated. Additionally, they generally are unable to access or navigate tortuous or small diameter vessels. Depending on the nature and extent of the occlusion, more than one successively larger balloon catheter may be required to sufficiently open the blockage so that it may accommodate the larger profile of the combination catheter.

In summary, a more flexible integrated product designed for use in all aspects of angioplasty and stent delivery would be desirable. Ideally such a product would be maneuverable through tortuous and small diameter vessels to more readily access occlusions. Such a product further would maximize efficiency, minimize catheter exchange and catheter profile, and aid in the reduction of abrupt reclosures.

SUMMARY OF THE INVENTION

The present invention relates to a single integrated product for performing multiple vascular procedures. Comprising two telescopic catheters, or a dual catheter assembly, the combination device is particularly suited for use in angioplasty and stent delivery.

The dual catheter assembly comprises a first balloon catheter and a second balloon catheter wherein the second catheter is slidably disposed on the shaft of the first catheter. In preferred embodiments, the first catheter is either a low profile balloon on a wire catheter or a low profile over the wire catheter. The second catheter is either an over the wire catheter or a single operator exchange catheter and has a plurality of balloons mounted thereon. A stent can be carried by at least one of the balloons on the second catheter. The first catheter may also have a plurality of balloons mounted thereon and can further include a stent mounted on one or more of the balloons. In more preferred embodiments, the second catheter includes a manifold that may be used to inflate and deflate any combination of the plurality of balloons *via* a single port or multiple ports.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a side view of one embodiment of the first catheter of the dual catheter assembly.

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Figure 2A is a cross section at position A-A of the first catheter illustrated by Figure 1.

Figure 2B is a cross section at position B-B of the first catheter illustrated by Figure 1.

Figure 3 is an enlarged view of the distal end of the first catheter illustrated by Figure 1.

Figure 4 is a side view of one embodiment of the second catheter of the dual catheter assembly.

Figure 5A is a cross section at position A-A of the second catheter illustrated by Figure 4.

Figure 5B is an enlarged side section of the second catheter illustrated by Figure 4 at a position where the proximal ends of the concentric balloons are mounted onto the catheter shaft.

Figure 5C is an enlarged side section of the second catheter illustrated by Figure 4 at a position where the distal ends of the concentric balloons are mounted onto the catheter shaft.

Figure 5D is a cross section at position D-D of the second catheter illustrated by Figure 4.

Figure 5E is an enlarged schematic of a valve gate that is used in the manifold illustrated by Figure 4.

Figure 5F is a side view of the manifold illustrated by Figure 4 wherein both valve gates are in the opened position.

Figure 5G is a side view of the same manifold as in Figure 5F wherein one of the valve gates is in the closed position.

5 Figure 6A is a side view of one embodiment of the dual catheter assembly wherein the second catheter is an over the wire catheter.

Figure 6B is a side view of a second embodiment of the dual catheter assembly wherein the second catheter is a single operator exchange catheter.

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Figure 6C is an enlarged view of the distal end of a third embodiment of dual catheter assembly wherein the second catheter includes two balloons in tandem wherein the most distal balloon of the second catheter also carries a stent thereon.

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Figure 7A is a fourth embodiment of the dual catheter assembly wherein the first catheter is a single balloon catheter and not a balloon on a wire catheter.

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Figure 7B is an enlarged side view of the distal end of the dual catheter assembly of Figure 7A.

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Figure 8A is a fifth embodiment of the dual catheter assembly which is similar to that illustrated by Figures 7A and 7B but with a different design for the second catheter.

Figure 8B is an enlarged side view of the distal end of the dual catheter assembly of Figure 8A.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

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The present invention relates to a dual catheter assembly, or a combination device that is particularly well suited for all aspects of both angioplasty and

stent delivery procedures. In the most general terms, the dual catheter assembly comprises a first balloon catheter and a second balloon catheter wherein the second catheter is slidably disposed on the shaft of the first catheter. Although not required for the practice of the present invention, it is preferred that the first catheter is a low profile balloon on a wire catheter, and the second catheter is a multiple balloon catheter which has at least one balloon that is larger than that mounted on the first catheter. Although either catheter may optionally carry a stent, it is generally preferred that the stent be carried by at least one of the balloons on the second catheter. In more preferred embodiments, the second catheter includes a manifold that may be used to inflate and deflate any combination of the plurality of balloons *via* a single port or multiple ports.

Figure 1 illustrates a preferred embodiment of a first catheter **10** which together with a second catheter forms the dual catheter assembly. First catheter **10** may be of any size (*i.e.* diameter and length) that may be useful in coronary procedures and comprises an elongated shaft **12** having a proximal end **14** and a distal end **16**.

Although not necessary to the practice of the present invention, it is generally preferred that first catheter **10** is a low profile catheter. In any event, the outside diameter of shaft **12** must be sufficiently small such that a second catheter may be slidably disposed over shaft **12**, and both catheters may be inserted into a coronary vessel.

Where the first catheter is a balloon on a wire catheter, the outside diameter of the elongated shaft is typically between about 0.005 and about 0.035 inches, more preferably between about 0.01 and about 0.015 inches, and a double wall thickness is typically between about 0.001 and about 0.015 inches, more preferably between about 0.001 and about 0.003 inches. Where the first catheter is an over the wire catheter, the outside diameter of the elongated shaft

is typically between about 0.010 and about 0.100 inches, more preferably between about 0.015 and about 0.030 inches, and a double wall thickness is typically between about 0.001 and about 0.040, more preferably between about 0.002 and about 0.010 inches. However, values for both the outside diameters and double wall thicknesses may be outside of these ranges.

Shaft **12** may be formed of any suitable material known in the art that is both sufficiently rigid and flexible to navigate the coronary passageways. Optionally, to prevent unnecessary vessel trauma, approximately about 15 to about 50 centimeters of the distal end **16** of shaft **12** can be more flexible than the remaining portion of shaft **12** so that catheter **10** may more easily yield when advanced against obstacles. This may be achieved by either using a different more flexible material or using a different processing method (while using the same material) than that used to form the remaining portion of shaft **12**.

Illustrative examples of suitable shaft materials include metals, such as stainless steel and shape memory alloys such as various nickel titanium blends (which are also known in the art as Nitinol), thermoplastic polymers, such as polyethylene and polystyrene, and polyamides, such as nylons. The outside surface of shaft **12** may optionally be coated with polymeric materials to provide a more lubricious surface to facilitate the navigation of catheter **10** through the coronary vessels.

The distal portion **16** of shaft **12** includes at least one balloon **18** mounted thereon. When catheter **10** is a low profile balloon on a wire catheter, distal portion **16** may optimally include floppy tip **20**. Balloon **18** may be formed of any suitable material known in the art. Illustrative examples include non-compliant materials such as polyethylene terephthalate and semi-compliant materials such as various homopolymers and copolymers of Nylon. Additives like plasticizers and stabilizers for manipulating balloon characteristics such as strength and processability may also be included.

The proximal and distal ends **22** and **24** of balloon **18** are bonded to shaft **12** using conventional methods like adhesives or thermal bonding (also known as heat sealing) to form a fluid tight seal. Because catheter **10** is typically a low profile catheter, balloon **18** mounted thereon typically will be smaller than those found on conventional catheters. In preferred embodiments, balloon **18** has a length between about 12 and about 30 millimeters, a double wall thickness between about 0.001 and about 0.003 inches, and an inflated diameter of between about 1.0 and about 4.0 millimeters, more preferably between about 1.5 and about 3.0 millimeters. In preferred embodiments, balloon **18** is capable of withstanding pressures of at least about 8 atmospheres and more preferably withstanding pressures between about 14 to about 20 atmospheres.

If more than one balloon is mounted on catheter **10**, it is preferred that the plurality of balloons are placed in tandem (one right behind another) after the most distal balloon **18** along the distal portion **16** of shaft **12**. In more preferred embodiments, each balloon added after the most distal balloon **18** is successively larger than the previously placed balloon. The tandem arrangement, in contrast to the concentric balloon arrangement, makes it more likely that catheter **10** will maintain its generally smaller profile.

When catheter **10** is a balloon on a wire catheter, floppy tip **20** is preferably attached at the most distal end **16** of shaft **12** using conventional means such as adhesives, thermal bonding, welding, soldering, and brazing, and is preferably formed of a suitable radiopaque material such as gold or a platinum tungsten alloy. A solder bead or weld **26** is attached to the distal end of floppy tip **20** to provide an atraumatic, hemispherical frontal surface.

As its name implies, floppy tip **20** is preferably more flexible than distal end **16** of shaft **12**, and may be of any suitable length. However, lengths between about 2 and about 8 centimeters are preferred and lengths between about 3 and about 5 centimeters are even more preferred. To maximize flexibility, floppy tip **20** in a

form of a coil as shown by Figure 1 is generally preferred. Optionally, floppy tip **20** may be manufactured with a slight bend (*i.e.* preshaped in a shape of a "J") to aid in steering catheter **10**. Alternatively, floppy tip **20** may be shaped into a desired bend by the catheter operator immediately before use.

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Attached to the most proximal end **14** of shaft **12** is fitting **28** which makes a fluid tight seal and includes at least one port **30** which is in communication with one or more lumens within shaft **12**. Illustrative examples of fitting **28** are a Touhy-Borst adapter which with a threaded cap which engages a sealing member and a Touhy-Borst adapter with a Luer lock. Fitting **28** may also be used as a means for applying torque and may optionally be removable from shaft **12**. For example, it may be desirable to remove fitting **28** to further extend the length of shaft **12** by conventionally attaching a guidewire extension thereon.

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Figure 2A is a cross-section of catheter **10** at position A-A which shows lumen **32** within shaft **12**. Figure 2B is a cross-section of catheter **10** at position B-B which shows balloon **18** surrounding shaft **12**. A radiopaque marker band **34** made from conventional materials is preferably disposed between proximal and distal ends **22** and **24** of balloon **18** so that the location of balloon **18** may be visualized while catheter **10** is being used.

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Figure 3 is an enlarged view of the distal end of catheter **10**. As illustrated by Figure 3, the portion of shaft **12** that is surrounded by balloon **18** may be optionally tapered to a smaller diameter than the remaining sections of shaft **12**.

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In addition, one or more slots **36** are formed in shaft **12** to provide access from the inflation/deflation port **30** through lumen **32** to balloon **18**. In preferred embodiments, shaft **12** contains a plurality of slots **36** so that balloon **18** may be rapidly inflated and deflated. In addition to providing access to balloon **18**, slots **36** also provide additional flexibility to distal end **16** of catheter **10**.

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Slots **36** may be of any suitable size. Illustrative examples include rectangular slots being spaced apart a distance of between about 1 and 4 millimeters, more preferably between about 2 and about 3 millimeters and having dimensions between about 0.5 and about 1 millimeters by between about 0.1 and about 0.5 millimeters. However, the length and width of the slots as well as their spacings may be outside of these ranges. Alternatively, slots **36** may be a single lead helical path.

Catheter **10** may optionally include a core wire. This core wire may extend the entire length of catheter **10** such that it extends through shaft **12** and floppy tip **20** (terminating into weld **26**), or may extend only a portion of catheter **10**. In preferred embodiments, core wire **38** is provided only at the distal end of catheter **10**. As illustrated by Figure 3, core wire **38** is attached to shaft **12** using conventional means such as adhesives and thermal bonding, and extends into a portion of floppy tip **20**.

Figure 4 illustrates a preferred embodiment of a second catheter **50** which together with the just described first catheter, forms the dual catheter assembly of the present invention. Although the second catheter depicted in Figure 4 is an over the wire ("OTW") catheter in which a guidewire is threaded through its entire length, the second catheter may also be a single operator exchange catheter ("SOE") in which a guidewire is threaded through only a portion of its distal length.

Second catheter **50** may be of any size (*i.e.* diameter and length) that may be useful in coronary procedures and comprises an elongated tubular member **52** having a proximal end **54** and a distal end **56**, and one or more balloons mounted thereon. Elongate tubular member **52** may be formed of any suitable material such as various thermoplastic polymers (*i.e.* polystyrene and polyethylene) and polyamides (*i.e.* Nylons). In preferred embodiments, the outside diameter of elongate tubular member typically is between about 0.025

and about 0.095 inches. An outside diameter of between about 0.035 and about 0.050 inches is especially preferred. The outside surface of elongate tubular member **52** may optionally be coated with polymeric materials to provide a more lubricious surface to facilitate the navigation of catheter **50** through the coronary vessels.

Although second catheter **50** may have any number of balloons, a plurality of balloons is generally preferred and may be formed from the same materials as previously described for the balloons mounted onto the first catheter. The plurality of balloons on second catheter **50** may be mounted on to elongated tubular member **52** in any arrangement. For example, the balloons may be in tandem, concentric, or a combination of both. In especially preferred embodiments and as depicted by Figure 4, catheter **50** includes at least two concentric balloons, **58** (outer balloon) and **60** (inner balloon) and carries a stent thereon.

In preferred embodiments, balloon **58** has a length typically between about 12 and about 45 millimeters and more preferably is between about 18 and about 30 millimeters, a double wall thickness typically between about 0.001 and about 0.015 inches, more preferably between about 0.001 and 0.003 inches, and an inflation diameter between about 1.5 and about 12 millimeters. Because balloon **60** is placed within balloon **58**, balloon **60** is necessarily smaller by between about 0.25 and about 2.0 millimeters, and has a length typically between about 11.5 and about 44.5 millimeters, and more preferably between about 17.5 and 29.5 millimeters, a double wall thickness typically between about 0.001 and about 0.015 inches, more preferably between about 0.001 and about 0.003 inches, and an inflation diameter between about 1 and about 12 millimeters. In preferred embodiments, balloons **58** and **60** are capable of withstanding pressures of at least about 8 atmospheres and more preferably between about 14 to about 20 atmospheres.

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Both balloons **58** and **60** are bonded to elongate tubular member **52** at the respective balloon's proximal and distal ends using conventional methods like adhesives or thermal bonding to form a fluid tight seal. One or more conventional radiopaque markers **62** and **64** are placed at the appropriate places along elongate tubular member **52** to help identify the position of balloons **58** and **60** during use. Optionally, one of the balloons on second catheter **50** may also carry a stent (not pictured by Figure 4).

Communication to the one or more balloons are provided via multiple lumens formed within elongate tubular member **52**. In preferred embodiments, a separate lumen is provided for each balloon mounted onto second catheter **50**. Figure 5A is a cross-section at position A-A of Figure 4 and shows three lumens, one for each of the two balloons (lumens **66** and **68**), and a third for the guidewire (lumen **70**).

Because the catheter depicted by Figure 4 is an over the wire catheter, lumen **70** extends through the entire length of elongated tubular member **52**. If second catheter **50** were a single operator exchange catheter, an exit port typically would exist approximately between about 20 and about 40 centimeters, more preferably about 30 centimeters from the distal end of elongate tubular member **52**.

Figures 5B and 5C are enlarged side sectional views of the proximal and distal ends of balloons **58** and **60**. As shown by Figure 5B, lumens **66** and **68** terminate near their respective balloon's proximal adhesion points **72** and **74** at which point the lumens essentially become coextensive with the interiors of balloon **58** and balloon **60** respectively. Because only guidewire lumen **70** still needs to be accommodated beyond adhesion points **72** and **74**, the diameter of the remaining portion of elongate tubular member **52** may be smaller than it was previously. Figure 5C illustrates such a scenario whereby the diameter of elongate tubular member **52** is only sufficient to accommodate guidewire lumen

70 at the distal adhesion points **76** and **78** of balloons **58** and **60**. This is also shown by Figure 5D which is a cross-section at position D-D of Figure 4 and shows that the only remaining lumen within elongate tubular member **52** after proximal adhesion points **72** and **74** is guidewire lumen **70**.

Referring back to Figure 4, proximal end **54** of elongate tubular member **52** is attached to manifold **80**. Optionally, elongate tubular member **52** may include strain relief **81** along its portion which spans the vicinity immediately both inside and outside of manifold **80**. Although any suitable manifold may be used with the dual catheter assembly, a manifold that allows any combination of the plurality of balloons to be independently inflated and/or deflated is generally preferred. This type of manifold is disclosed by U.S. Serial No. 09/014,532 filed January 28, 1998 entitled "MULTIPLE VALVE SINGLE PORT MANIFOLD" by inventors Thomas Michael Bourne, Anant Hegde, and Harm TenHoff which is incorporated herein by reference.

Manifold **80** comprises (i) conduit **82** having entry port **84**; (ii) shaft **86** for containing elongated tubular member **52** therein, shaft **86** optionally having guidewire entry port **88** (for when second catheter **52** is an over the wire catheter); and, (iii) a plurality of valve gates **90** disposed within conduit **82** having an opened and a closed position.

Conduit **82** includes entry port **84** and a plurality of valve housings **92** for each valve gate **90**, and is fluidly coupled to shaft **86** by connectors **94**. Shaft **86** in turn includes a plurality of base channels **96** for continuing the connection to the balloon inflation/deflation lumens of elongate tubular member **52**. At each junction where elongate tubular member **52** and base channel **96** meet within shaft **86**, elongate tubular member **52** includes an opening to the corresponding balloon inflation/deflation lumen (lumens **66** or **68** which are not depicted by Figure 4). As a result, when valve gates **90** are in an opened position, entry port **84** is fluidly coupled to balloon inflation lumens **66** and **68** via conduit **82**

through connectors **94** and base channels **96**.

Independent access to each balloon inflation lumen from a single entry port **84** is possible by a unique design for valve gate **90**. As shown by Figure 5E, valve gate **90** comprises handle **98** and stem **100**. Stem **100** in turn includes seals **102** at its upper and lower portions, upper horizontal channel **104**, lower horizontal channel **106**, and vertical channel **108**. Upper horizontal channel **104** and lower horizontal channel **106** are in different horizontal planes and are placed at an angle, preferably 90° , with respect to each other. However, an essential feature of the valve gate design is the placement of the upper horizontal channel **104** and lower horizontal channel **106** along stem **100** such that both are capable of being in fluid communication with conduit **82**. Lower horizontal channel **106** is fluidly coupled to vertical channel **108**, preferably connecting at 90° with respect to each other to form a T-shaped passageway.

Operation of the valve gate will be further discussed with reference to Figures 5F and 5G. As shown by Figures 5F, because the proximal valve gate **98A** with respect to entry port **84** is in an opened position, entry port **84** is fluidly coupled to its corresponding balloon inflation lumen via lower horizontal channel **106A** and vertical channel **108A**. Proximal lower horizontal channel **106A** also acts as a pass through channel to the distal valve gate **98B**. Distal valve gate **98B**, also being in an opened position is fluidly coupled to its corresponding balloon inflation lumen in a similar manner. The arrows indicate the direction of fluid flow.

When proximal valve gate **98A** is in a closed position (as depicted by Figure 5G), upper horizontal channel **104A** is fluidly coupled to entry port **84**. Because upper horizontal channel is not coupled to vertical channel **108A**, it can only act as a pass through channel to the distal valve gate **98B**. As shown by Figure 5G, lower horizontal channel **106B** is fluidly coupled to vertical channel **108B** which in turn allows access to the corresponding balloon inflation lumen. The

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combination of upper horizontal channel **104** and lower horizontal channel **106** allows each valve gate to control access to its corresponding catheter lumen without regard to the positions of the other valve gates.

5 Manifold **80** may be made of any suitable material known in the art. In preferred embodiments, rigid materials, such as polycarbonate and styrene, that are not easily compressible are preferred for forming the conduit **82**, valve housings **92**, shaft **86**, connectors **94** and base channels **96**. However, since some compressibility is desired for forming a tight seal between valve gates **90** and valve housings **92**, slightly less rigid materials, such as polyethylene and
10 polypropylene, are preferred for making the valve gates **90**.

Figures 6A and 6B illustrates two embodiments of the dual catheter assembly of the present invention. Both first and second catheters in both Figures are
15 generally similar to those previously described. However, Figure 6A shows a dual catheter assembly **110** wherein the second catheter is an over the wire catheter and Figure 6B shows a dual catheter assembly **120** wherein the second catheter is a single operator exchange catheter. Similarly, Figure 6C illustrates the distal end of a third embodiment **130** of the present invention. In this
20 embodiment, the first catheter **132** is as previously described wherein it is a low profile single balloon on a wire catheter. However, second catheter **136** is a dual balloon catheter wherein balloons **138** and **140** are in a tandem arrangement. The most distal balloon or balloon **138** also carries stent **142** thereon.

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Operation of the dual catheter assembly of the present invention will be illustrated with reference to the specific embodiment depicted by Figure 6A. The combination device may be packaged pre-assembled (wherein the second catheter is slidably disposed over the first catheter) or may be assembled from
30 the component pieces by a technician or physician immediately prior to the angioplasty procedure. If desired, a stent may be mounted onto an appropriate

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balloon, preferably on second catheter **50**, by crimping it by hand or by a crimping device. The dual catheter assembly is then introduced into the patient using conventional procedures.

5 Once the dual catheter assembly is in the general vicinity of the stenosis or an especially tortuous site, only the first catheter typically is advanced further to take advantage of its generally smaller profile while the second catheter remains behind. Once at the stenosed site, balloon **18** of catheter **10** is inflated and deflated to partially open the occluded vessel. Optionally, catheter **10** includes a
10 plurality of balloons which are preferably arranged in tandem, each balloon typically being successively larger in diameter than its distally neighboring balloon so that the doctor may have a variety of balloon sizes from which to choose from. In general, when the stenosis is sufficiently pre-dilated to accommodate the larger sized catheter **50**, the one or more balloons of first
15 catheter **10** are advanced distally beyond the affected site.

Second catheter **50** is then advanced to the site by sliding it over shaft **12** of catheter **10**. The stent is delivered by inflating either one of the concentric balloons **58** or **60** (or both in succession) depending on the circumstances.

20 Optionally, second catheter **50** includes one or more additional balloons located more distally than concentric balloons **58** and **60** which may be used to further dilate the stenosis before stent delivery. Alternatively, second catheter **50** may include one or more additional balloons located more proximally than concentric balloons **58** and **60** which may be used for various post-dilation
25 procedures. Each balloon on second catheter **50** may be independently inflated and deflated from entry port **84** of manifold **80**. The dual catheter assembly, comprising first catheter **10** and second catheter **50**, is removed from the patient when all the procedures are completed.

30 If pre-assembly is not desired, the catheters which comprise the dual catheter assembly may be put together *in situ*. For example, a balloon on a wire first

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catheter **10** is introduced into the occluded vessel to pre-dilate the stenosis.

Once this completed, fitting **28** is removed and a guidewire extension is attached (if necessary) so that shaft **12** may be used as a stand alone guidewire for second catheter **50**. At this point, second catheter **50** is threaded over shaft **12** starting from the proximal end of shaft **12** toward its distal end as catheter **50** is navigated to the stenosis. When properly situated, second catheter **50** is used in the same manner as previously described.

Figures 7A and 7B show another embodiment of the dual catheter assembly wherein the first catheter is not a balloon on a wire catheter. As shown by Figure 7A, this embodiment **150** comprises first catheter **152** and second catheter **154**. First catheter **152** includes elongated shaft **156** having guide wire lumen and balloon inflation lumen therethrough (lumens not pictured). First catheter **152** further comprises balloon **162** at its distal end, and removable fitting **164** having guide wire port **166** and balloon inflation port **168** at its proximal end. Second catheter **154** comprises elongated shaft **170**, balloon **172** carrying stent **174** thereon, and fitting **176**. Fitting **176** includes port **178** for receiving shaft **156** of first catheter **152**, inflation lumen **180**, and flush port **182**.

Because first catheter **152** is not also a guide wire, an independent guide wire (which is threaded through first catheter **152**) is required during use of this inventive embodiment. With the exception of the requirement for an independent guide wire, operation of this embodiment is as previously described.

Figures 8A and 8B show yet another embodiment of the dual catheter assembly wherein the first catheter is not a balloon on a wire catheter. As shown by Figure 8A, this embodiment **200** comprises first catheter **202** and second catheter **204**. First catheter **202** is similar to that previously described in Figure 7 and includes elongated shaft **206** having guide wire lumen and balloon inflation lumen therethrough (lumens not pictured). First catheter **202** further comprises balloon **212** at its distal end, and removable fitting **214** having guide

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wire port **216** and balloon inflation port **218** at its proximal end. Second catheter **204** comprises elongated shaft **220**, inner balloon **222**, outer balloon **224**, stent **226** carried by outer balloon **224**, and manifold **228** which is similar to that previously depicted by Figures 4 and 5. Manifold **228** allows any combination of inner and outer balloons to be inflated and deflated, and includes valve gates **230**, inflation lumen **232**, flush port **234**, and port **236** for receiving shaft **206** of first catheter **202**. Because first catheter **202** is not an independent guide wire, an independent guide wire (which is threaded through first catheter **202**) is also required during use of this inventive embodiment. With the exception of the requirement for an independent guide wire, operation of this embodiment is also as previously described.

Although the dual catheter assembly and its method of use has been described with reference to particular embodiments, it should be understood that various features of the preferred embodiments may be used in any suitable combination. For example, a preferred device feature may be entirely eliminated such as coiled floppy tip **20** by replacing it with an extension of shaft **12**. Similarly, even an especially preferred feature like a stent mounted on the second catheter may be entirely eliminated from the dual catheter assembly. In some situations, it may be desirable to mix the stated preferences between the first and second catheters. For example, a stent may be placed on a balloon on the first catheter instead of a second catheter, or multiple stents may be placed on balloons of either or both of the first or second catheters. In another example, first catheter may be a multiple lumen balloon catheter having a manifold similar to that described for second catheter **50** instead of fitting **28**. Accordingly, although the present invention has been described with reference to preferred embodiments, it should be appreciated that these embodiments are for purposes of illustration only and are not intended to limit the scope of the appended claims.

What is claimed is:

1. A dual catheter assembly comprising:
a first catheter wherein the first catheter includes
5 a shaft having a distal end and a proximal end;
a first balloon mounted on the distal end of the
shaft; and
means for inflating the first balloon,
and
10 a second catheter slidably disposed on the first catheter, the
second catheter including
an elongate tubular member having a distal end
and a proximal end;
a plurality of balloons mounted on the distal end
15 of the elongate tubular member; and,
means for inflating the plurality of balloons.
2. The dual catheter assembly as in claim 1 wherein the first catheter also
functions as a guidewire.
20
3. The dual catheter assembly as in claim 2 wherein the first catheter has
extension capability.
4. The dual catheter assembly as in claim 2 wherein the first catheter
25 further includes a floppy tip.
5. The dual catheter assembly as in claim 4 wherein the floppy tip is
preshaped.
- 30 6. The dual catheter assembly as in claim 4 wherein the floppy tip is
shapeable before use.

7. The dual catheter assembly as in claim 1 wherein in the first catheter includes a plurality of balloons.

5 8. The dual catheter assembly as in claim 7 wherein the first catheter further includes a stent mounted onto one of the plurality of balloons.

9. The dual catheter assembly as in claim 1 wherein the first catheter is a low profile balloon on a wire catheter.

10 10. The dual catheter assembly as in claim 1 wherein the first catheter further includes a removable fitting mounted on the proximal end of the shaft wherein the fitting includes a port for inflating and deflating the first balloon.

15 11. The dual catheter assembly as in claim 10 wherein the removable fitting also acts as a torquer.

12. The dual catheter assembly as in claim 1 wherein the first catheter further includes a non-removable fitting mounted on the proximal end of the shaft wherein the fitting includes a port for inflating and deflating the first balloon and wherein the fitting prevents the removal of the second catheter over the proximal end of the first catheter.

20 13. The dual catheter assembly as in claim 1 wherein the first catheter further includes a stent.

14. The dual catheter assembly as in claim 1 wherein the second catheter further includes a stent, the stent mounted onto one of the plurality of balloons.

25 15. The dual catheter assembly as in claim 14 wherein the second catheter has two balloons, a second balloon and a third balloon.

16. The dual catheter assembly as in claim 15 wherein the third balloon placed within the second balloon.

5 17. The dual catheter assembly as in claim 16 wherein the stent is carried by the second balloon.

18. The dual catheter assembly as in claim 15 wherein the second balloon and the third balloon are arranged in tandem with the third balloon proximal to the second balloon.

19. The dual catheter assembly as in claim 18 wherein stents are mounted onto the second and the third balloons.

15 20. The dual catheter assembly in claim 18 wherein the second balloon has a larger inflation diameter than the third balloon.

21. The dual catheter assembly as in claim 15 wherein the third balloon has a larger inflation diameter than the second balloon.

20 22. The dual catheter assembly as in claim 1 wherein the second catheter is an over the wire catheter.

23. The dual catheter assembly as in claim 1 wherein the second catheter is a single operator exchange catheter.

24. The dual catheter assembly as in claim 1 wherein the second catheter further includes a separate lumen formed within the elongate tubular member for each balloon mounted thereon.

25. The dual catheter assembly as in claim 1 wherein the second catheter

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further includes a manifold mounted on to the proximal end of the elongate tubular member, the manifold comprising:

- a passageway for receiving the elongate tubular member;
- a conduit having an entry port; and
- 5 a plurality of valves disposed within the conduit,

wherein at least two of the valves have an opened position and a closed position, and include a first channel and second channel formed therein, the first channel in communication with the conduit to provide access through the valve when the valve is placed in the closed position, and the second channel in
10 communication with the conduit to provide access through the valve as well as to fluidly couple the conduit to the passageway when the valve is placed in the opened position.

26. The dual catheter assembly as in claim 25 wherein the manifold valve
15 includes a handle and an elongated stem and the elongated stem includes the first channel and the second channel.

27. The dual catheter assembly as in claim 26 wherein the first channel is substantially linear and the second channel is a T-shaped passageway.

28. The dual catheter assembly as in claim 1 wherein the second catheter further includes a manifold secured to the proximal end of the elongate tubular member, the manifold comprising:

- a passageway for receiving the elongate tubular member;
- 25 a conduit having an entry port; and
- a plurality of valves disposed within the conduit,

wherein each valve has an opened position and a closed position to provide access through the valve and fluidly couple the conduit to the passageway when the valve is placed in the opened position.

29. A dual catheter assembly comprising:

23

a first catheter wherein the first catheter includes

a shaft having a distal end and a proximal end;

a first balloon mounted on the distal end of the
shaft; and

means for inflating the first balloon,

and

a second catheter slidably disposed on the first catheter, the
second catheter including

an elongate tubular member having a distal end

and a proximal end;

a second balloon mounted on the distal end of the
elongate tubular member;

a stent carried by the second balloon; and,

means for inflating the second balloon.

30. The dual catheter assembly as in claim 29 wherein the first catheter also
functions as a guidewire.

31. The dual catheter assembly as in claim 30 wherein the first catheter has
extension capability.

32. The dual catheter assembly as in claim 29 wherein the second catheter
includes one or more additional balloons.

33. The dual catheter assembly as in claim 32 wherein the second catheter
includes one or more additional stents mounted onto one or more of the
additional balloons.

34. The dual catheter assembly as in claim 32 wherein the second catheter
has two balloons.

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35. The dual catheter assembly as in claim 34 wherein the two balloons are in a concentric arrangement.

36. A dual catheter assembly

a first catheter wherein the first catheter includes

a shaft having a distal end and a proximal end;

a first balloon mounted on the distal end of the

shaft; a stent mounted onto the first balloon; and,

means for inflating the first balloon,

and

a second catheter slidably disposed on the first catheter, the second catheter including

an elongate tubular member having a distal end

and a proximal end;

at least one balloon mounted on the distal end of

the elongate tubular member; and,

means for inflating the at least one balloon.

37. The dual catheter assembly as in claim 36 wherein the second catheter has a stent mounted on at least one balloon.

38. A kit comprising:

a first catheter wherein the first catheter includes

a shaft having a distal end and a proximal end;

a first balloon mounted on the distal end of the

shaft; and

means for inflating the first balloon,

and

a second catheter capable of being slidably disposed on the first catheter, the second catheter including

an elongate tubular member having a distal end

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and a proximal end;

a plurality of balloons mounted on the distal end

of the elongate tubular member; and,

means for inflating the plurality of balloons.

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39. The kit as in claim 38 further comprising one or more stents capable of being mounted on one or more balloons.

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40. The kit as in claim 38 further comprising one or more stents carried by one or more balloons.

41. A kit comprising:

a first catheter wherein the first catheter includes

a shaft having a distal end and a proximal end;

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a first balloon mounted on the distal end of the shaft; and

means for inflating the first balloon,

and

a second catheter capable of being slidably disposed on the first catheter, the second catheter including

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an elongate tubular member having a distal end

and a proximal end;

a second balloon mounted on the distal end of the elongate tubular member;

25

a stent carried by the second balloon; and,

means for inflating the second balloon.

42. The kit as in claim 41 wherein the second catheter includes one or more additional balloons.

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43. The kit as in claim 42 further comprising one or more stents capable of

being mounted on the one or more additional balloons.

44. The kit as in claim 42 further comprising one or more additional stents carried on the one or more additional balloons.

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45. A method for treating stenosis in a blood vessel of a patient using a dual catheter assembly having a first catheter and a second catheter wherein the first catheter includes a shaft having a distal end and a proximal end; a first balloon mounted on the distal end of the shaft; and means for inflating the first balloon; and wherein the second catheter is capable of being slidably disposed on the first catheter and the second catheter includes an elongate tubular member having a distal end and a proximal end; a plurality of balloons mounted on the distal end of the elongate tubular member; and means for inflating the plurality of balloons, the method comprising:

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positioning the first balloon at the stenosis;

inflating and deflating the first balloon;

positioning one of the plurality of balloons on the second catheter at the stenosis and inflating and deflating said balloon.

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46. The method as in claim 45 wherein the positioning step of the one of the plurality of balloons on the second catheter involves advancing the second catheter over the shaft of the first catheter.

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47. The method as in claim 45 wherein the positioning step of the one of the plurality of balloons on the second catheter involves advancing the first balloon at a site distal to the stenosis prior to advancing the second catheter over the shaft of the first catheter.

30

48. The method as in claim 45 wherein the positioning step of the one of the plurality of balloons on the second catheter involves simultaneously advancing both the first catheter and the second catheter.

49. The method as in claim 45 further comprising inflating and deflating another one of the plurality of balloons on the second catheter.

5 50. The method as in claim 45 wherein the second catheter has two balloons, a second balloon and a third balloon.

51. The method as in claim 50 wherein the second balloon is within the third balloon.

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52. The method as in claim 45 wherein the second catheter further includes a stent mounted onto one of the plurality of balloons, the method further comprising the steps of

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positioning the balloon carrying the stent at the stenosis and inflating and deflating said balloon to deploy the stent.

53. The method of claim 52 further comprising the step of positioning any of the plurality of balloons at the stenosis and inflating and deflating said balloon subsequent to the step of deploying the stent.

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54. The method as in claim 45 wherein the first catheter includes one or more additional balloons, the method further comprising

positioning one of the additional balloons on the first catheter at the stenosis and inflating and deflating said additional balloon.

25

55. The method as in claim 52 wherein the first catheter includes one or more additional balloons, the method further comprising the steps of

positioning one of the additional balloons on the first catheter at the stenosis and inflating and deflating said additional balloon subsequent to the step of deploying the stent.

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56. A method for treating stenosis in a blood vessel of a patient using a dual catheter assembly having a first catheter and a second catheter wherein the first catheter includes a shaft having a distal end and a proximal end; a first balloon mounted on the distal end of the shaft; and means for inflating the first balloon; and wherein the second catheter is capable of being slidably disposed on the first catheter and the second catheter includes an elongate tubular member having a distal end and a proximal end; a second balloon and a third balloon mounted on the distal end of the elongate tubular member; a stent carried on the third balloon; and means for inflating the second and third balloons, the method comprising:

positioning the first balloon at the stenosis;
inflating and deflating the first balloon;
positioning the second balloon at the stenosis; and
inflating and deflating the second balloon

57. The method as in claim 56 wherein the positioning step of the second balloon involves advancing the second catheter over the shaft of the first catheter.

58. The method as in claim 56 wherein the positioning step of the second balloon involves advancing the first balloon at a site distal to the stenosis prior to advancing the second catheter over the shaft of the first catheter.

59. The method as in claim 56 wherein the positioning step of the second balloon involves simultaneously advancing both the first catheter and the second catheter.

60. The method as in claim 56 wherein the second balloon is within the third balloon and the inflation of the second balloon expands the stent onto the said blood vessel.

61. The method as in claim 60 further comprising inflating and deflating the third balloon.

62. The method of claim 56 further comprising the steps of
5 positioning the first, second or third balloon at the stenosis subsequent to the expansion of the stent onto the blood vessel; and
inflating and deflating said first, second or third balloon.

63. A method for treating stenosis in a blood vessel of a patient using a dual
10 catheter assembly having a first catheter and a second catheter wherein the first catheter includes a shaft having a distal end and a proximal end; a first balloon mounted on the distal end of the shaft; and means for inflating the first balloon; and wherein the second catheter is capable of being slidably disposed on the
15 first catheter and the second catheter includes an elongate tubular member having a distal end and a proximal end; a second balloon and a third balloon mounted on the distal end of the elongate tubular member wherein the second balloon is within the third balloon; a stent carried on the third balloon; and means for inflating the second and third balloons, the method comprising:
positioning the first balloon at the stenosis;
20 inflating and deflating the first balloon;
positioning the stent at the stenosis; and
inflating and deflating the third balloon to expand the stent onto the blood vessel.

64. The method as in claim 63 wherein the positioning step of the stent involves advancing the second catheter over the shaft of the first catheter.

65. The method as in claim 63 wherein the positioning step of the stent involves advancing the first balloon distal to the stenosis prior to advancing the
30 second catheter over the shaft of the first catheter.

30

66. The method as in claim 63 wherein the positioning step of the stent involves simultaneously advancing both the first catheter and the second catheter.

5 67. The method of claim 63 further comprising the steps of
positioning the first, second or third balloon at the stenosis subsequent
to the expansion of the stent onto the blood vessel; and
inflating and deflating said first, second or third balloon.

10 68. A method for treating stenosis in a blood vessel of a patient using a dual
catheter assembly having a first catheter and a second catheter wherein the first
catheter includes a shaft having a distal end and a proximal end; a first balloon
mounted on the distal end of the shaft; means for extending the shaft; and means
for inflating the first balloon; and wherein the second catheter is capable of
15 being slidably disposed on the first catheter and the second catheter includes an
elongate tubular member having a distal end and a proximal end; a plurality of
balloons mounted on the distal end of the elongate tubular member; and means
for inflating the plurality of balloons, the method comprising:

20 positioning the first balloon at the stenosis;
inflating and deflating the first balloon;
positioning one of the plurality of balloons of the second catheter at the
stenosis and inflating and deflating said balloon;
extending the shaft of the first catheter;
removing the second catheter over the extended shaft of the first
25 catheter; and
advancing a third catheter over the shaft of the first catheter.

30 69. A method for treating stenosis in a blood vessel of a patient using a dual
catheter assembly having a first catheter and a second catheter wherein the first
catheter includes a shaft having a distal end and a proximal end; a first balloon
mounted on the distal end of the shaft; a stent mounted onto the first balloon;

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and means for inflating the first balloon; and wherein the second catheter is capable of being slidably disposed on the first catheter and the second catheter includes an elongate tubular member having a distal end and a proximal end; at least one balloon mounted on the distal end of the elongate tubular member; and means for inflating the at least one balloon, the method comprising:

positioning the stent at the stenosis;

inflating and deflating the first balloon to expand the stent onto said blood vessel;

positioning the at least one balloon of the second catheter at the stenosis and inflating and deflating said balloon to further expand the stent.

70. A method for treating stenosis in a blood vessel of a patient using a dual catheter assembly having a first catheter and a second catheter

wherein the first catheter includes a shaft having a distal end and a proximal end; one or more first catheter balloons mounted on the distal end of the shaft; and means for inflating the one or more first catheter balloons; and

wherein the second catheter is capable of being slidably disposed on the first catheter and the second catheter includes an elongate tubular member having a distal end and a proximal end; one or more second catheter balloon mounted on the distal end of the elongate tubular member; and means for inflating the one ore more second catheter balloon; and

wherein one or more stents are mounted on one or more of the first or second catheter balloons, the method comprising the steps of:

positioning at least one stent at the stenosis; and

inflating and deflating the balloon carrying the stent to expand and deploy the stent onto said blood vessel.

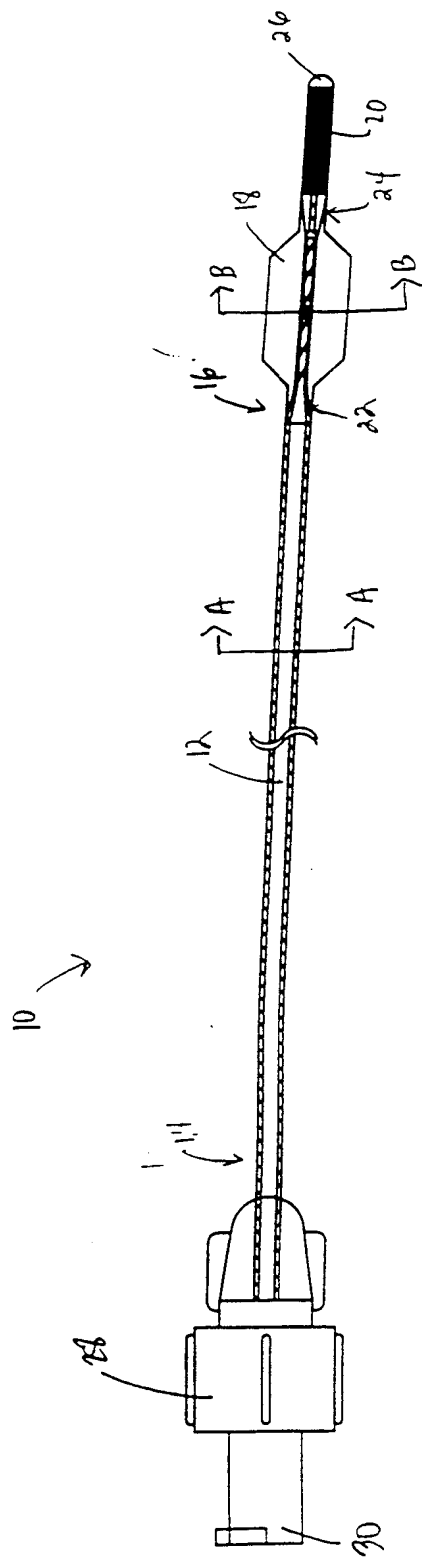
71. The method of claim 70 further comprising the steps of:

positioning another first or second catheter balloon at the stenosis prior to positioning the stent and inflating and deflating said another balloon.

72. The method of claim 70 further comprising the steps of positioning one of the first or second catheter balloons at the stenosis after deploying the stent, and inflating and deflating said balloon.

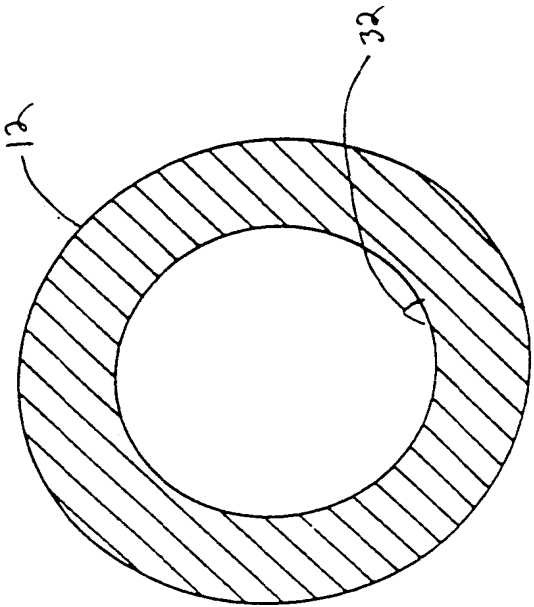
5 73. The method of claim 71 further comprising the steps of positioning one of the first or second catheter balloons at the stenosis after deploying the stent, and inflating and deflating said balloon.

Figure 1



CROSS SECTION "AA"

Figure 2A



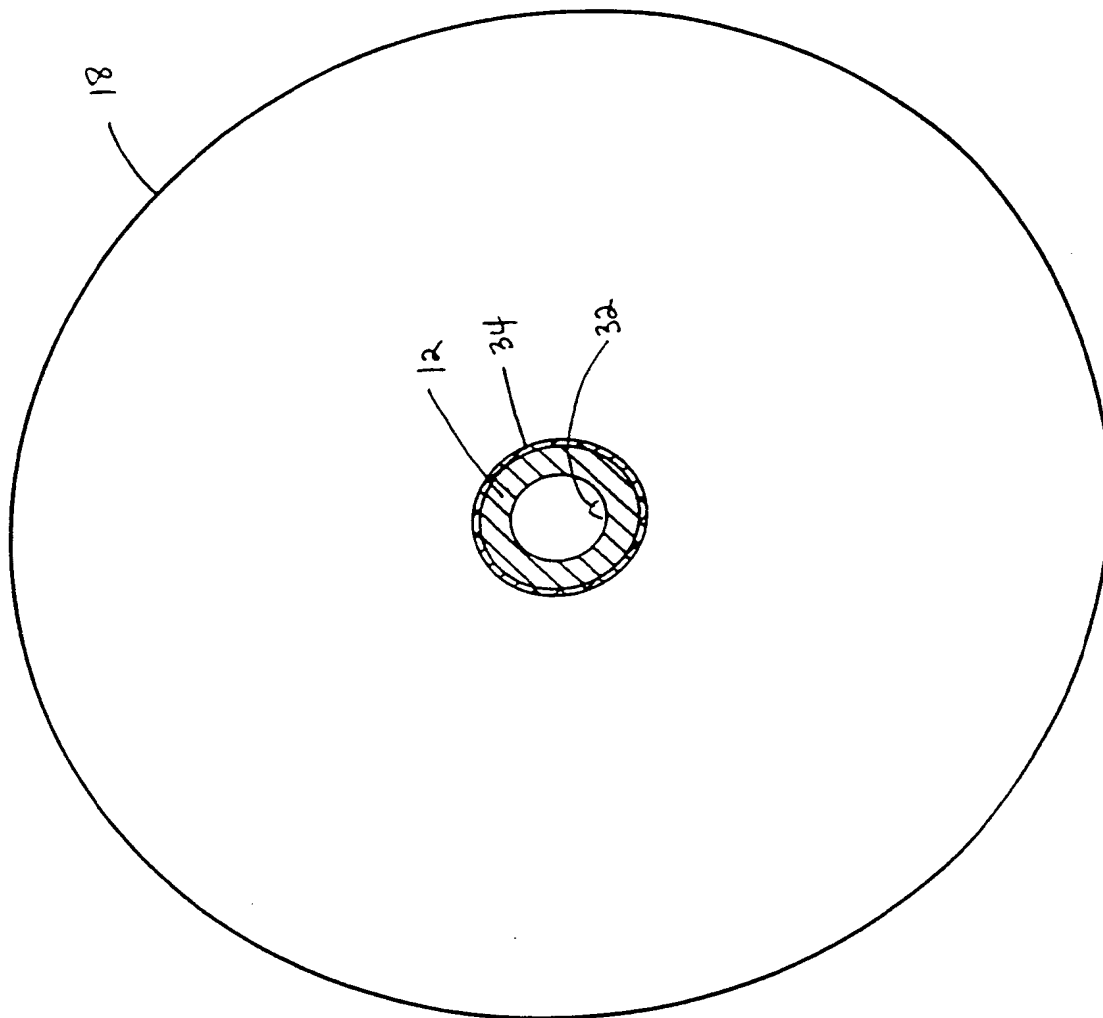


Figure 2B

Figure 3

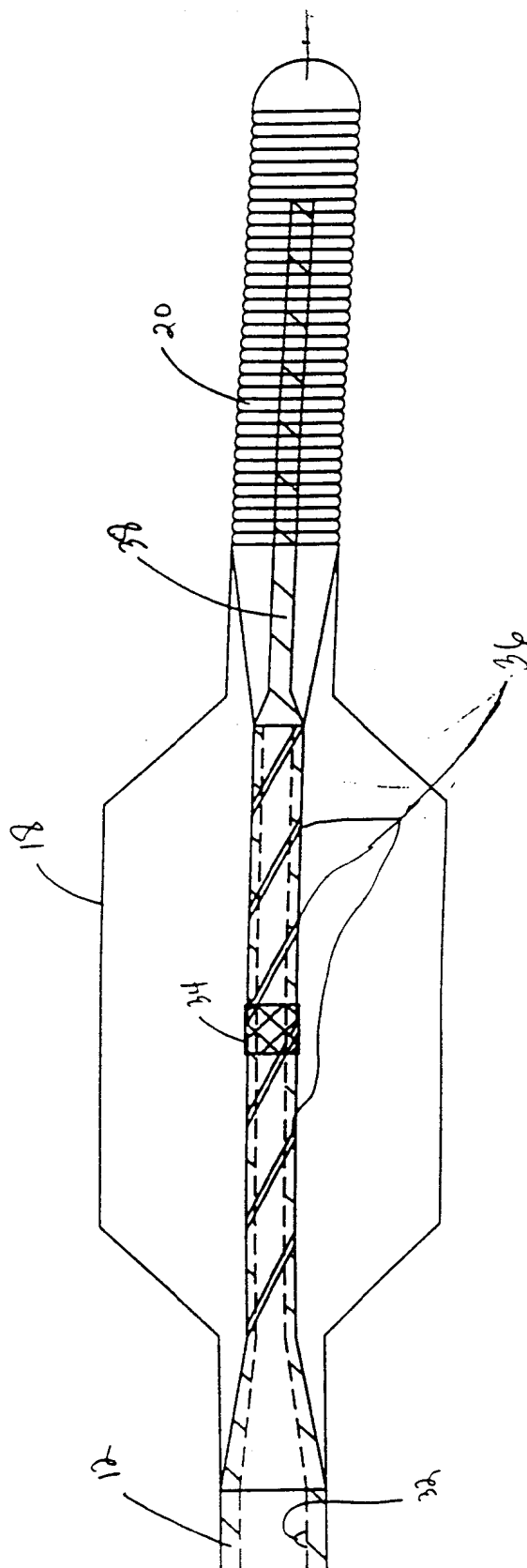
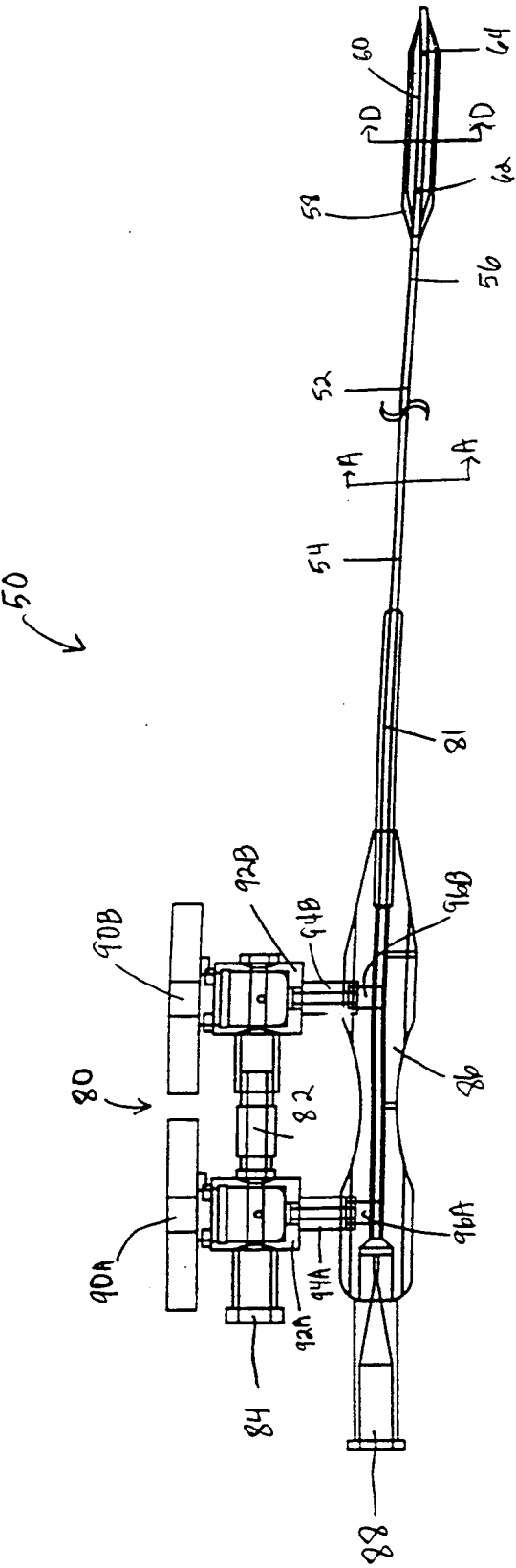


Figure 4



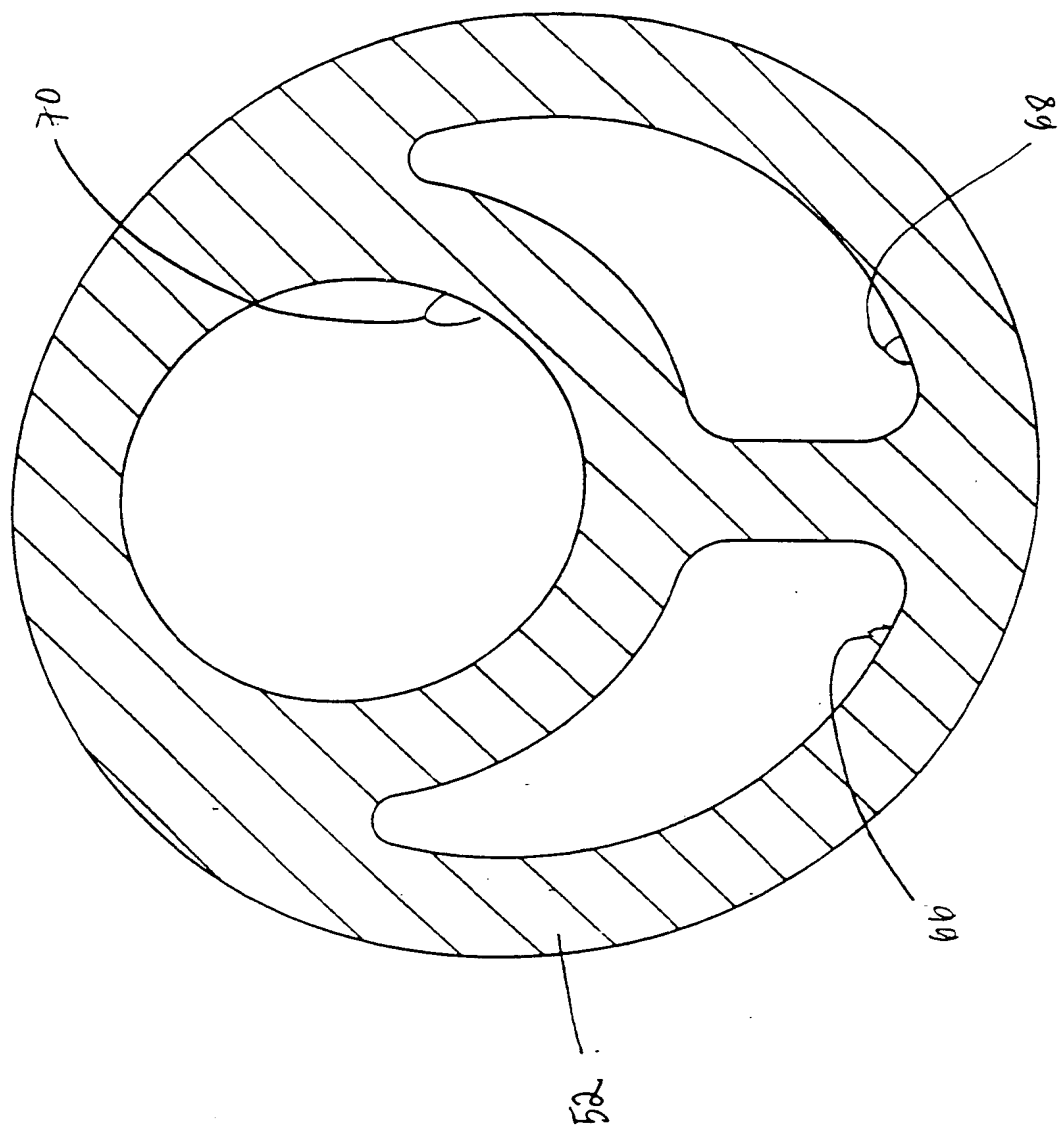


Figure 5A

Figure 5b

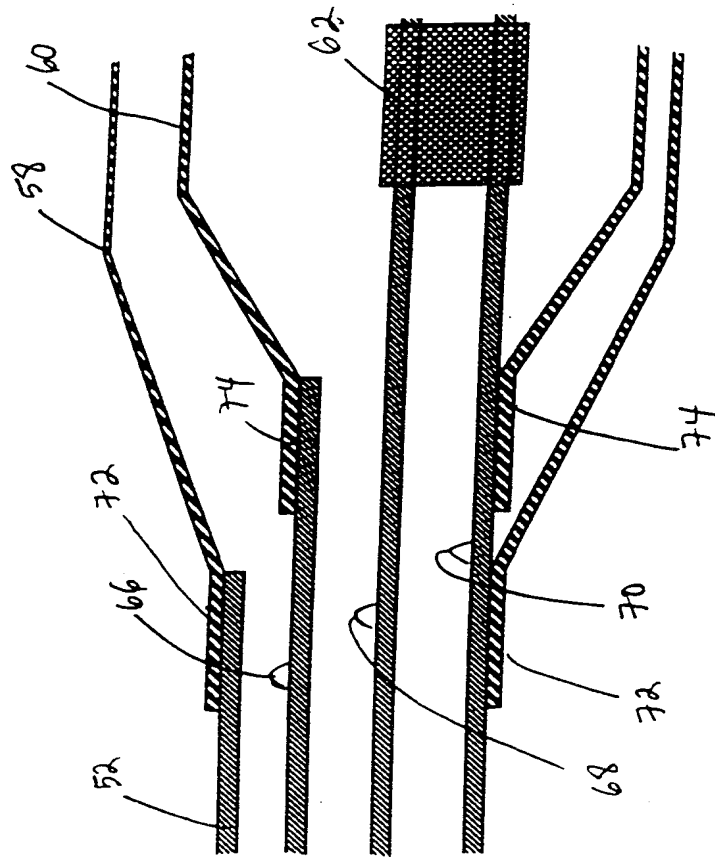
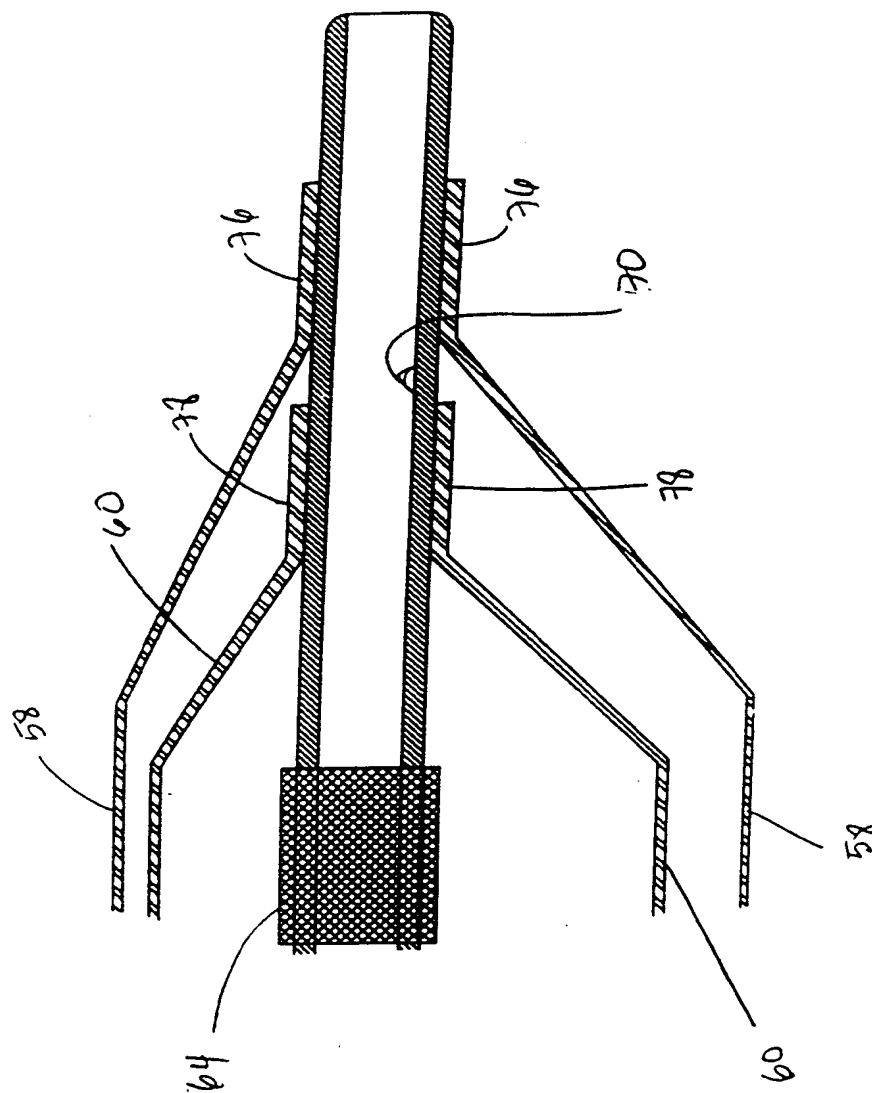


Figure 5C



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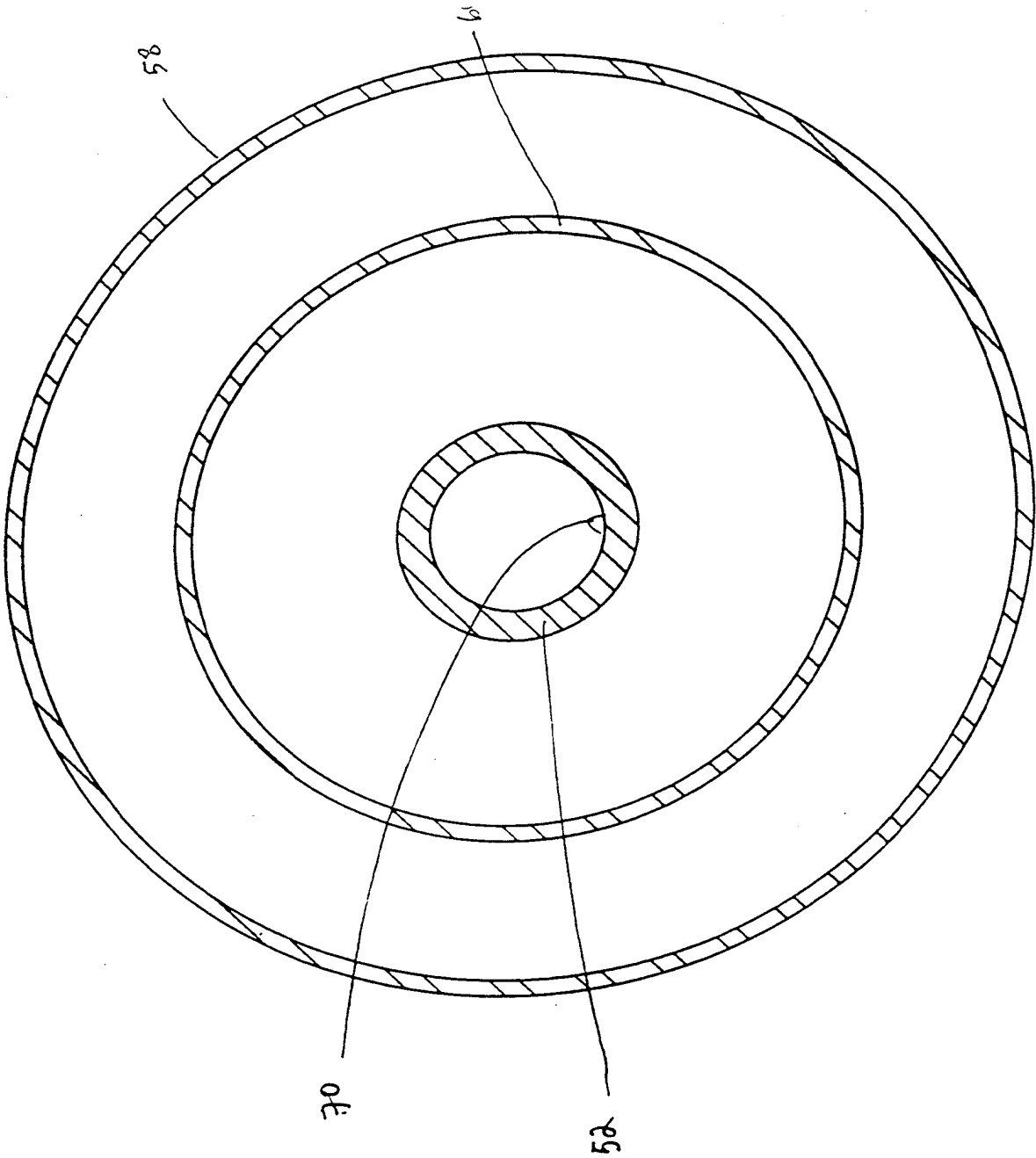
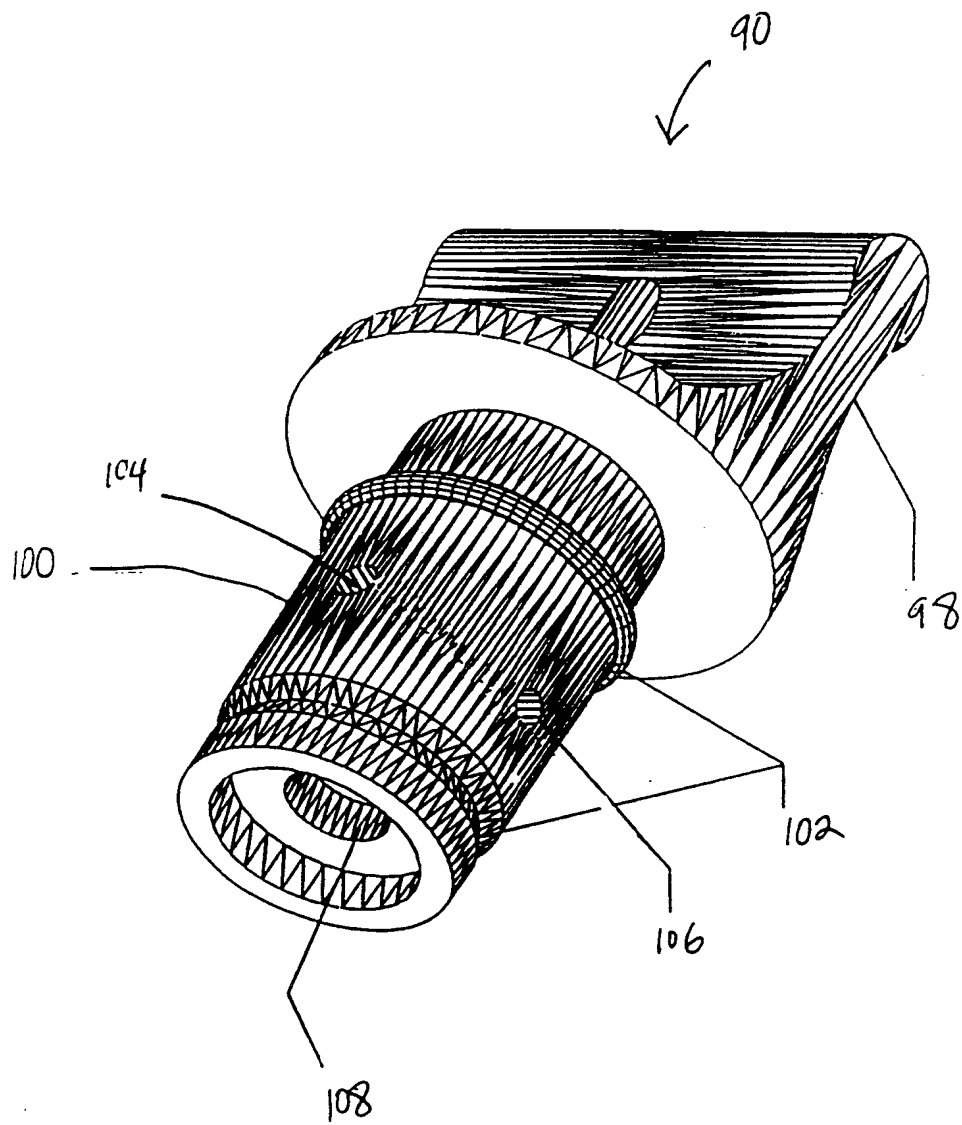


figure 50

Figure 5E



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figure 56

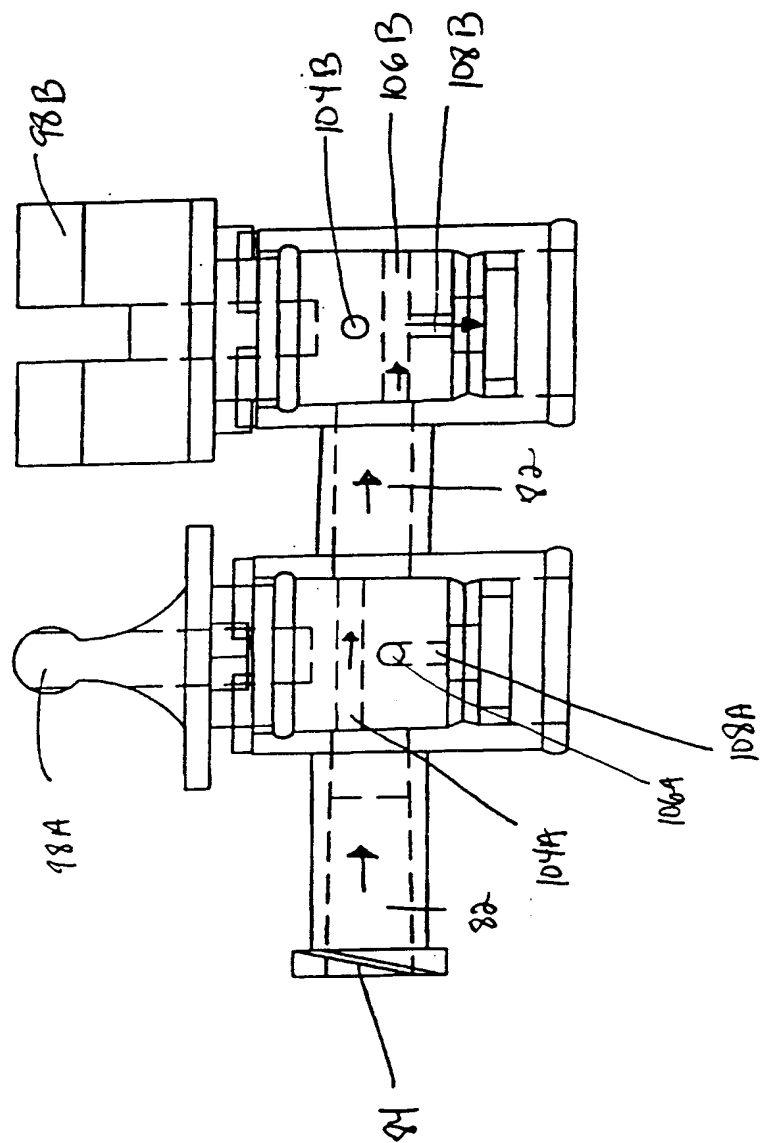


Figure 6A

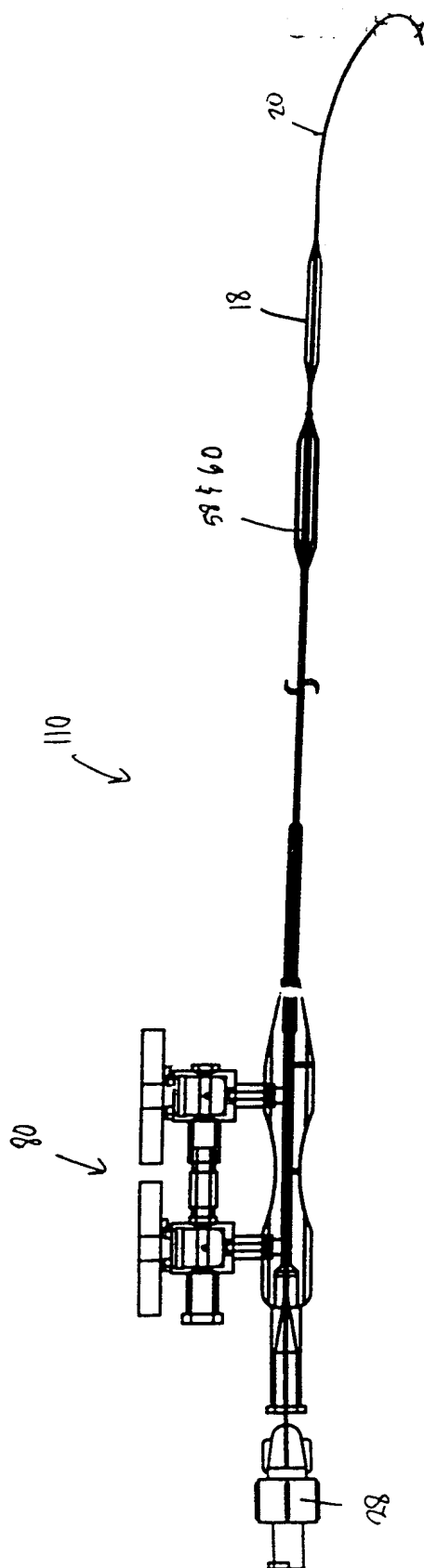


Figure 6b

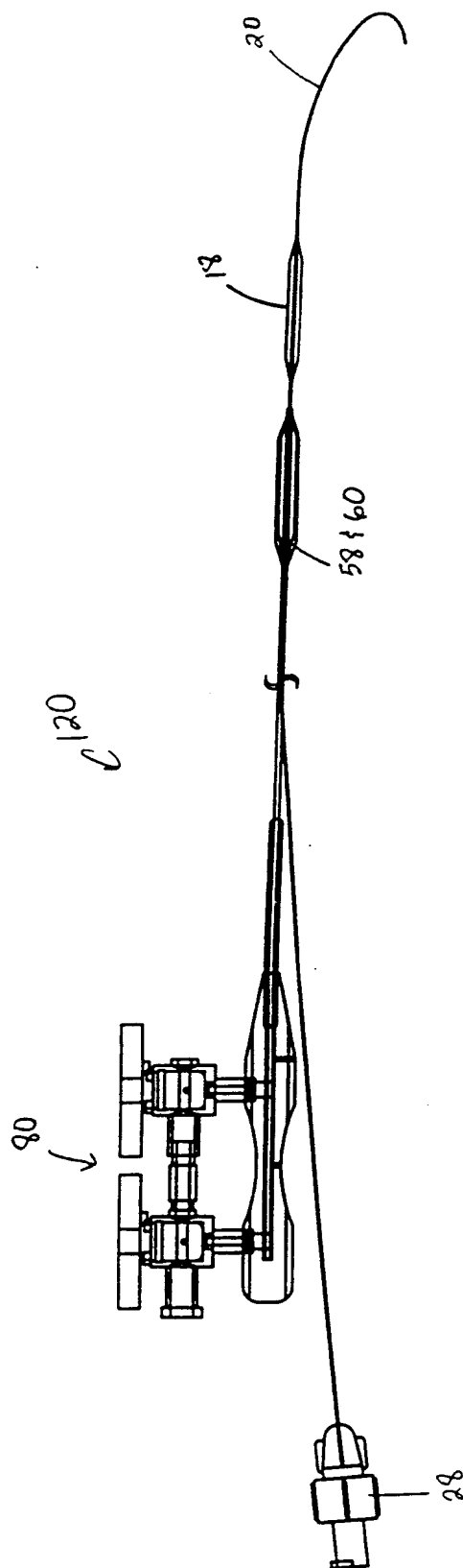


Figure 6C

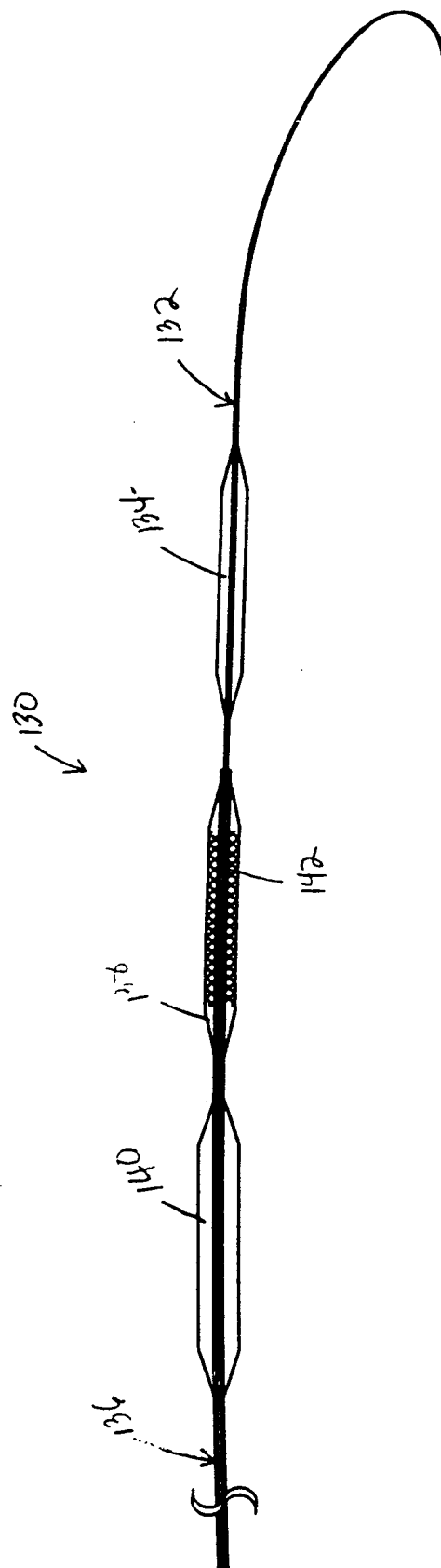


Figure 7B

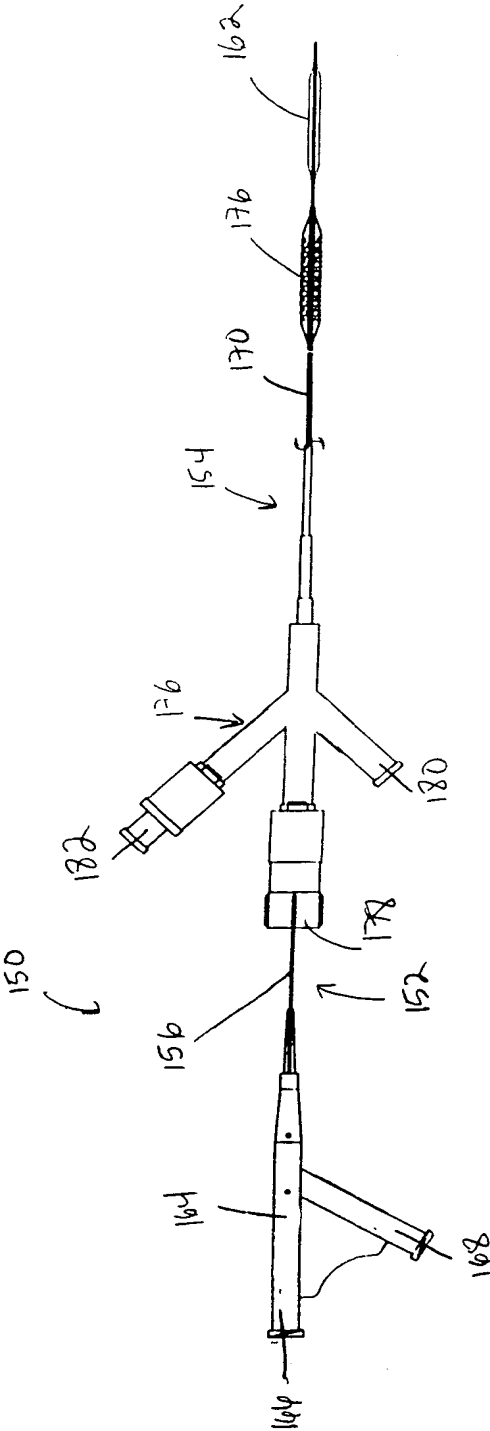
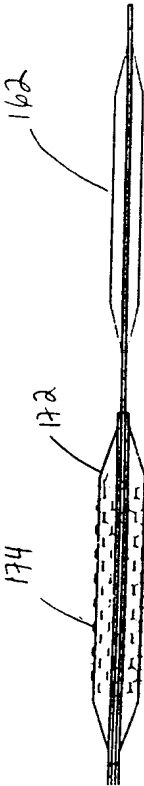


Figure 7A

Figure 8B

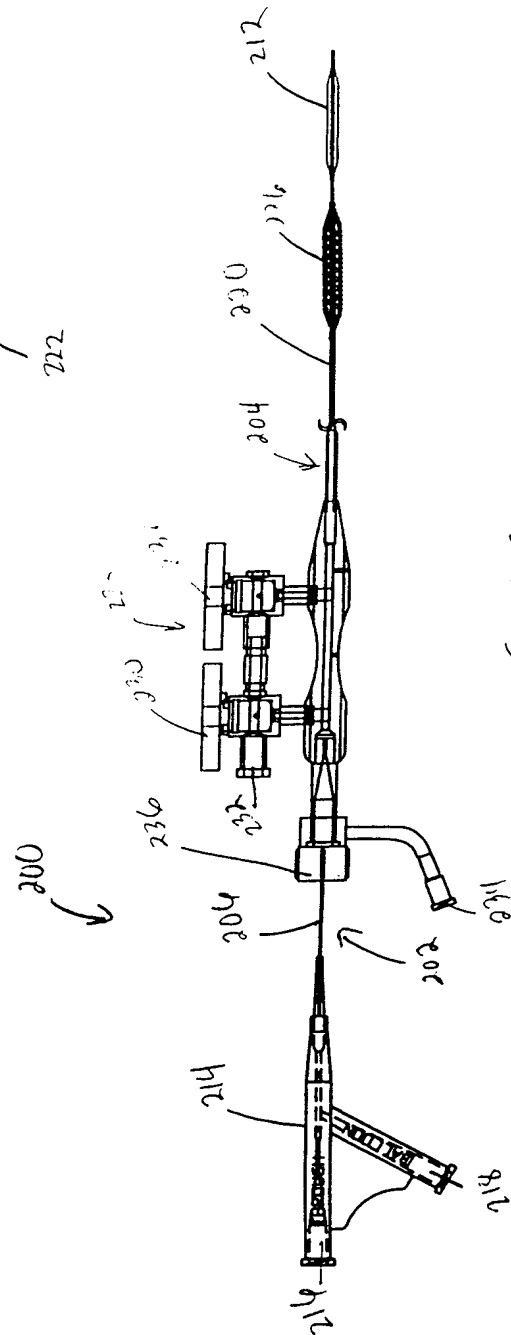
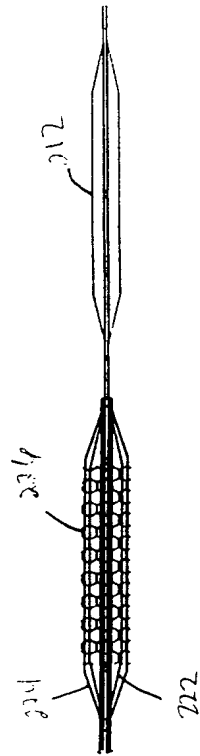


Figure 8A